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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/027,404	12/19/2001	William A. McMillan	22660-0025 D1 C1	2514

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EXAMINER

SISSON, BRADLEY L

ART UNIT PAPER NUMBER

1634

DATE MAILED: 01/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

10/027,404

Applicant(s)

MCMILLAN ET AL.

Examiner

Bradley L. Sisson

Art Unit

1634

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 30 November 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 30 November 2004. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the _____ application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 1-6 and 50-94.

Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____.



Bradley L. Sisson
Primary Examiner
Art Unit: 1634

Continuation of 2. NOTE: The response of 30 November 2004 states that it is an amendment, however, a review of the document fails to locate where any claim, or portion of the specification has been amended. Rather, the document appears to represent claims from the response of 04 February 2004. Accordingly, the response has been construed as a request for reconsideration of both the rejections/objections, and the holding of finality.

Continuation of 5. does NOT place the application in condition for allowance because: No convincing evidence has been presented that overcomes all objections and rejections.

At page 12 of the response received 30 November 2004, hereinafter the response, appellant's representative asserts that the finality of the Office action mailed 01 July 2004 is improper and should be withdrawn. In support of this position appellant's representative draws attention to amendments made to claim 1, and only claim 1. This argument has not been found persuasive as it fails to address the addition of claims 63-94 and that claims 6, 50, and 52-62 had also been amended. Secondly, the instant application has been appealed. Even if appellant's argument were persuasive towards the withdrawal of the holding of finality, such would not undue or negate the case from being on appeal for as set forth in MPEP at 1205, any claim that has been twice rejected can be basis for sending the application up on appeal. Clearly, there is at least one claim pending that has been twice rejected. Therefore, regardless of finality, the case is under appeal and appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

Acknowledgement is made of applicant having indicated that other applications are currently pending before the Office as well as some that have been abandoned and/or issued as US Patents. While all five applications were pending before the Office prior to the filing of the instant application, appellant's representative's disclosure of same did not take place until subsequent to closing of prosecution on the merits of the instant application. Accordingly, these documents have not been considered on the merits.

At page 13 of the response appellant's representative asserts that the objection to the specification should be withdrawn, inter alia, the fact pattern in the instant application is distinguishable over that of the cited cases. This traversal has been fully considered and has not been found persuasive. Attention is also directed to MPEP 608.01(p)I, which, in pertinent part, is reproduced below:

"Mere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 U.S.C. 112, first paragraph. In re de Seversky, 474 F.2d 671, 177 USPQ 144 (CCPA 1973). In addition to other requirements for an application, the referencing application should include an identification of the referenced patent, application, or publication. Particular attention should be directed to specific portions of the referenced document where the subject matter being incorporated may be found."

Accordingly, the cited documents are not considered to have been properly incorporated by reference and as such, have not been considered with any effect towards their fulfilling, either in part or in whole, the enablement, written description, or best mode requirements of 35 USC 112, first paragraph.

At pages 14-15 of the response appellant's representative asserts that the claimed apparatus does not necessarily have to comprise any apparatus that actually carries out an amplification reaction, but rather, "the claimed apparatus can be used in conjunction with other devices or elements."

The above argument has been fully considered and has not been found persuasive towards the withdrawal of the rejection. While applicant may well assert that in one embodiment the claimed apparatus can be used in conjunction with some other device, the claims fairly encompass having an amplification means integral to the claimed apparatus, or "in conjunction" with the device, or not present in any manner. It is further noted that appellant's representative, at page 15, first paragraph, of the response, admits that "the apparatus may include a vessel and/or an element acted on by the controller." While appellant's representative has directed attention to where the original disclosure provides support for detector and controller elements, the aspect of avoiding issues of new matter have not been found to rise to the level of reasonably suggesting that applicant was in possession of the full genera of apparatus encompassed by the claims. Therefore, and in the absence of convincing evidence to the contrary, the rejection is maintained.

At page 15, bridging to page 16 of the response appellant's representative asserts that the amplification reaction vessel "need not necessarily be part of the apparatus." As shown above, however, appellant's representative has asserted that the claims do fairly encompass such embodiments. Agreement is reached in that appellant's representative that the specification as filed does not provide support for an infinite number of elements (response at page 15, last paragraph), an interpretation that the Office holds that the claims do fairly encompass.

Agreement is reached in that there is no per se rule that an appellant must limit claims to a certain set of sizes or shapes, or to only their preferred embodiment. However, the claims, given their broadest reasonable interpretation, must also be fully supported by the disclosure. In the present case the claims fairly encompass an apparatus of any dimension, and complexity. A review of the disclosure fails to locate a full, clear, and concise description of the claimed apparatus that would support such breadth of scope. Accordingly, the narrowing of the scope of the claims to those embodiments adequately supported by the disclosure is encouraged.

Appellant's representative, at page 16 of the response, presents traversal of the rejection of claims under 35 USC 112, first paragraph, as failing to comply with the enablement requirement. As presented at page 8 of the prior Office action, the subject application fails to reasonably suggest that applicant was in possession of the invention at the time of filing, and that one cannot enable that which they do

not yet possess. Accordingly, and in the absence of convincing evidence to the contrary, claims 1-5 and 50-94 are not enabled by the instant disclosure.

Agreement is reached in that a specification need not enable or exemplify each and every possible permutation encompassed by the claims. Yet, the specification must fully enable the claims. As shown above, appellant's representative asserts that the claimed invention encompasses apparatus that comprise an amplification vessel over which the controller exerts control, as well as apparatus that "can be used in conjunction with other devices" (response at page 14, last paragraph, bridging to page 15). The instant disclosure is found to provide but three examples: "Example 1- External Standards," pages 94-96; "Example 2- Quantitative Internal Controls," pages 96-99; and "Example 3- Internal Standards," pages 99-101. None of these examples teach formulae to be used in conducting first, second, or subsequent derivatized growth curves so that positive and/or negative peaks are obtained, (limitations of claims 1-4) etc., which in turn is applied in a useful and reproducible manner for any and all manner of amplification reactions that are occurring in any amplification vessel, be they under the control of the "controller" or under some other and as yet undefined vessel and controlled means. In view of the tremendous breadth of the claims, the limited guidance found in the specification, and the absence of convincing evidence to the contrary, claims 1-5 and 50-94 remain rejected under 35 USC 112, first paragraph, and failing to comply with the enablement requirement.

At page 17 of the response appellant's representative asserts that it is inappropriate to require elements that would exercise control over various aspects of performing an amplification reaction, e.g., volume of reagents, as the claims do not require the presence of an amplification vessel.

The above argument has been fully considered and has not been found persuasive towards the withdrawal of the rejection for as noted at page 15 of the response, appellant's representative states that the claims encompass just such an embodiment.

At page 18, bridging to page 19 of the response appellant's representative traverses the rejection of claims under 35 USC 101, yet appellant's representative agrees that the claims do encompass the embodiment described in the rejection. Further, argument presented fails to provide convincing evidence as to how the claimed apparatus is to function when there is no amplification vessel integral the claimed apparatus. Therefore, and in the absence of convincing evidence to the contrary, the rejection is maintained.

At page 18, bridging to page 19 of the response appellant's representative asserts that "claims of the '297 patent are directed to an apparatus with a controller programmed to use quantitate internal controls for quantitation of nucleic acids and not, a stated by the Office, to determine threshold cycle number."

The above traversal has been fully considered and has not been found persuasive towards the withdrawal of the rejection. It is noted that the instant claims are sufficient broad of scope so to encompass the use of quantitative internal controls. Further, claims 21 and 22, which depend from claim 1 of US Patent 6,713,297, require that one calculate a threshold cycle number, a limitation of the claimed invention. Given that an independent claim encompasses the limitation of its dependent claim, claim 1 '297 patent is also considered to encompass just such a limitation. Therefore, and in the absence of convincing evidence to the contrary, the rejection is maintained.